

Customer No. 28880

Confirmation No.

PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/662,046
	Filing Date	September 11, 2003
	First Named Inventor	Bolton, et al.
	Art Unit	1626
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	PC 25006A

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to a Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Statement as Provided by 37 CFR 1.97(b)
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	Return Postcard
<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	AUTHORIZATION TO CHARGE THE FEE AND ANY ADDITIONAL FEES AS NECESSARY OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT 23-0455 IS HEREBY GIVEN.	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

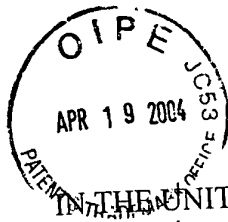
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual	Cynthia M. Bott
Signature	<i>Cynthia M. Bott</i>
Date	4-13-04

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date <u>4/13/04</u>	
Typed or printed	Cynthia D. Bernges
Signature	<i>Cynthia D. Bernges</i>
Date	4/13/04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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USPTO Fax No. 703-872-9306



PC 25006A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/662,046  
Applicant : Bolton, et al.  
Filed : September 11, 2003  
Title : "INHIBITORS OF FACTOR Xa AND OTHER SERINE PROTEASES INVOLVED IN THE COAGULATION CASCADE"  
TC/AU : 1626  
Examiner : Not Yet Assigned  
Docket No. : PC25006A  
Customer No. : 28880

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))**

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

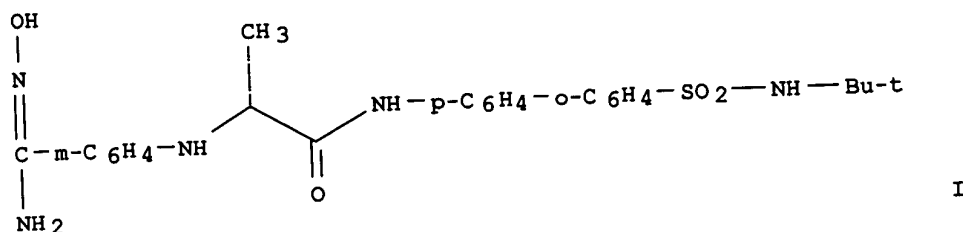
The Information Disclosure Statement submitted herewith is being filed before the mailing of the first Office Action on the merits.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

A concise explanation of the relevance of each non-English language document or other information is as follows (37 C.F.R. §1.98(a)(3)):

WO 02/30880: WO 02/30880 discloses N-substituted amino acid derivative compounds of formula I, as described therein, which are suitable as inhibitors of blood coagulation factor Xa. For example, D-alanine was condensed with 3-iodobenzonitrile to give (2R)-2-(3-cyanophenylamino)-propionic acid, which was then reacted with 4'-aminobiphenyl-2-sulfonic acid tert-Bu amide to give (2R)-N-(2'-tert-butylsulfamoylbiphenyl-4-yl)-2-(3-

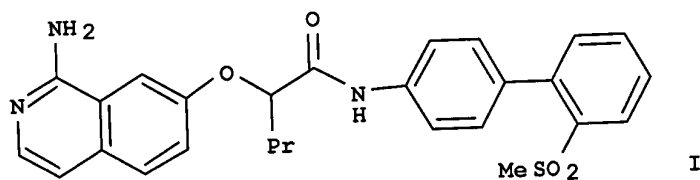
cyanophenylamino)-propionic acid amide (II). The cyano group of II was then reacted with hydroxylamine hydrochloride to give I.



WO 02/08177: Applicants note that a corresponding US application, US2003/0162814, has published in English (identified by Micropatent family search).

WO 02/48099: Applicants note that a corresponding US application, US2004/0038858, has published in English (identified by Micropatent family search).

WO 02/24654: WO 02/24654 discloses biphenyl-substituted aminoquinoline and isoquinoline derivative compounds of Formula I, as described therein, which are suitable as inhibitors of blood coagulation factors Xa and VIIa. For example, 7-isoquinolinol was treated with  $\text{BrCHPrCO}_2\text{CMe}_3$ , followed by ester hydrolysis, amidation with 2- $\text{MeSO}_2\text{C}_6\text{H}_4\text{C}_6\text{H}_4\text{NH}_2$ -4, N-oxide., reaction with pyridine, and treatment with ethanolamine to give the title compd. I.



No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. §1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form

1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

It is understood by the Applicants that this paper requires no fee; however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Authorization is hereby given to charge the required fee under 37 C.F.R. §1.17(p), any other necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully Submitted,

Dated: 4-13-04



Cynthia M. Bott, J.D., Ph.D.  
Registration No. 46,568  
Warner -Lambert Company  
2800 Plymouth Road  
Ann Arbor, Michigan 48105  
Telephone: (734) 622-4476  
Facsimile: (734) 622-1553



PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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**Complete if Known**

Application Number	10/662,046
Filing Date	September 11, 2003
First Named Inventor	Bolton, et al
Art Unit	1626
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25006A

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 4559157	December 17, 1985	Smith, et al.	
		US- 4608392	August 26, 1996	Jacquet, et al.	
		US- 4820508	April 11, 1989	Mitchell S. Wortzman	
		US- 4938949	July 3, 1990	Borch, et al.	
		US- 4992478	February 12, 1991	Geria, et al.	
		US- 5807875	September 15, 1998	Rudolf, et al.	
		US- 2004/0038858	February 26, 2004	Dorsch, et al.	
		US- 2003/0162814	August 28, 2003	Juraszyk, et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 01/64642 A2	09/07/01	Cortheraapeutics, Inc.		
		WO 01/96296 A1	12/20/01	Eli Lilly and Company		
		WO 02/057236 A1	07/25/02	Merck Patent GMBH		
		WO 02/08177 A2	01/31/02	Merck Patent GMBH		
		WO 02/24654 A1	03/28/02	Merck Patent GMBH		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 5

**Complete if Known**

Application Number	10/662,046
Filing Date	September 11, 2003
First Named Inventor	Bolton, et al.
Art Unit	1626
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25006

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 02/30880 A2	04/18/02	Merck Patent GMBH		
		WO 98/007718 A1	02/26/98	Warner-Lambert Company		
		WO 98/50029 A1	11/12/98	University of Pittsburgh		
		WO 97/05161 A1	02/13/97	Sandoz Ltd.		
		WO 97/19911 A1	06/05/97	Dr. Karl Thomae GMBH		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

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**Complete if Known**

Application Number	10/662,046
Filing Date	September 11, 2003
First Named Inventor	Bolton, et al
Art Unit	1626
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25006A

**U. S. PATENT DOCUMENTS**

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		US-			
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**FOREIGN PATENT DOCUMENTS**

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		WO 97/46576 A1	12/11/97	Gyogyszerkutato Intezet		
		WO 95/28420 A1	10/26/95	Corvas International Inc.		
		WO 02/48099 A1	06/20/02	Merck Patent GMBH		
		CA 23/99018	08/30/01	Merck Patent GMBH		

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete If Known</b>	
				Application Number	10/662,046
				Filing Date	September 11, 2003
				First Named Inventor	Bolton, et al
				Art Unit	1626
				Examiner Name	Not Yet Known
Sheet	4	of	5	Attorney Docket Number	PC 25006A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BERGE S.M. ET AL., Pharmaceutical Salts, Journal of Pharmaceutical Science, 1977;66:1- 19	
		EDMUNDS et al., Annual Reports in Medicinal Chemistry, 1996, p. 51	
		ERIK VERNER et al.: "Development of Serine Protease Inhibitors Displaying a Multicenter Short Hydrogen Bond Binding Mode: Inhibitors of Urokinase-Type Plasminogen Activator and Factor Xa" JOURNAL OF MEDICINAL CHEMISTRY Vol 44, no. 17, 2001, Pages 2753-2771, XP002216503	
		F AL-OBEIDI & JAOSTREM: "Factor Xa Inhibitors" EXPERT OPINION ON THERAPEUTIC PATENTS., Vol 9, No. 7, 1999, Pages 931-953, XP001000512	
		FIORAVANTI et al., Thromb. Res., 1993, pp. 317-324	
		FIORAVANTI et al., Thromb. Res., 1993, pp. 317-324	
		KUNITADA and NAGAHAREA, Curr. Pharm. Des., 1996, pp 531-542	
		LAPATTO et al., Embo. J, 1997, pp. 5151-5161	
		LEADLEY, Curr. Top. Med. Chem., 2001, Vol. 1, pp. 151-159	
		LYNCH et al., Thromb. Haemostasis, 1995, pp 640-645	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/662,046
Filing Date	September 11, 2003
First Named Inventor	Bolton, et al.
Art Unit	1626
Examiner Name	Not Yet Known
Attorney Docket Number	PC 25006A

Sheet

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of

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MELLOTT et al., Fibrinolysis, 1993, pp. 195-202	
		MICHAEL R WILEY et al., "Structure-Based Design of Potent, Amidine-Derived Inhibitors of Factor Xa: Evaluation of Selectivity, Anticoagulant Activity, and Antithrombotic ctivity" JOURNAL OF MEDICINAL CHEMISTRY, vol 43, no. 5, 2000, pages 883-899, XP002186966	
		SCHAFFER et al., Circulation, 1991, pp. 640-645	
		WONG et al., Thromb. Res., 1996, pp. 317-32	
		YING K. YEE et al., "N-Aroylantranilamide Inhibitors of Human Factor Xa" JOURNAL OF MEDICINAL CHEMISTRY, vol. 43, no 5, 2000, pages 873-882, XP002186	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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